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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,792	11/20/2001	Andrzej W. Lipkowski	18475-025 (NEMC-6)	9119
7590		04/19/2005	EXAMINER	
Ingrid A. Bcattie		FORD, VANESSA L		
Mintz, Levin, Cohn, Ferris,		ART UNIT		
Glovsky and Popeo, P.C.		PAPER NUMBER		
One Financial Center		1645		
Boston, MA 02111		DATE MAILED: 04/19/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/988,792	Applicant(s) LIPKOWSKI ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,40-43 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,40-43 and 47-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>2/16/2005</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2005 has been entered. Claims 1030, 32-39, 44-46 and 52-54 have been cancelled. Claims 31, 40-43 and 44-46 have been amended.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

3. The following rejections are withdrawn in view of Applicant's amendment and response.

a) rejection of claims 31-43 and 47-54 under 35 U.S.C. 102(b), pages 3-6, paragraph 4 of the Final Office action.

b) rejection of claims 31-39, 47 and 52-53 under 35 U.S.C.103(a), pages 6-7, paragraph 5 of the Final Office action.

c) objection of claim 35, page 7, paragraph 8 of the Final Office action.

d) objection of claims 40-33, page 7, paragraph 8 of the Final Office action.

e) rejection of claims 32 and 33 under 35 U.S.C.112, second paragraph, page 7, paragraph 8 of the Final Office action.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 11. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 31, 40-43 and 47-51 are rejected under 35 U.S.C. 102(b) as anticipated by Yankner (*U.S. Patent No. 5,876,948 published March 2, 1999*).

Claims 31, 40-43 and 47-51 are drawn to a composition comprising a fragment of a substance P peptide, wherein said fragment comprises antimicrobial activity and does not bind to a cell surface substance P peptide receptor, and wherein said fragment consists of residues 1-8 of SEQ ID NO:1 and a composition comprising a fragment of a substance P peptide, wherein said fragment comprises antimicrobial activity and does not bind to a cell surface substance P peptide receptor, and wherein said fragment consists of residues 1-8 of SEQ ID NO:2.

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Yankner teaches a composition comprising a fragment of a substance P peptide (tachykinin agonists) which consists of the first eight amino acid residues of SEQ ID NO:

1. Yankner teaches that this P peptide fragment is set forth in SEQ ID NO: 57 (column 35). Yankner also teaches a fragment of a substance P peptide that consists of the first eight amino acid residues of SEQ ID NO: 2 by teaching that the substance P fragments of the invention may have an amino acid substitution of tyrosine (Tyr) for phenylalanine (Phe) (column 7). Yankner teaches that the substance P fragments are therapeutic (column 10). Claim limitations such as "wherein said fragment comprises antimicrobial activity and does not bind to a cell surface substance P receptor" would be inherent in the teachings of the prior art. Claim limitations such as "wherein the said dose comprises at least 44 μ M of substance P peptide" or "about 44 μ M to about 10 mM of substance P peptide" or "about 44 μ M to about 390 μ M of substance P peptide" are being viewed as limitations of design choice since Yankner teaches that the amount of agonists to be administered will vary dependent upon the agonist and can be determined by standard procedures (column 10). Claim limitations such as "wherein said composition further comprises a bandage or patch into which the fragment is incorporated" or wherein said composition further comprises a gel, cream, lotion, ointment, aerosol or suppository are being viewed as limitations of design choice since Yankner teaches that the peptides can be administered topically (column 10).

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the

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product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

6. No claims are allowed.

Conclusion

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
April 13, 2005


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